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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,805	02/21/2002	William E. Ortyn	BIOL0038	2051

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,805	ORTYN ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,35,37-40,42-44,46,49-51,54 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,35,37-40,42-44,46,49-51,54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed on June 2, 2006, is acknowledged and has been entered. Claim 41, 45, 47, 48, 52, and 53 have been cancelled. Claims 34, 35, 37, 39, 40, 42, 43, 45, 46, and 51 have been amended. Claims 54 and 55 have been added. Accordingly, claims 34, 35, 37-40, 42-44, 46, 49-51, 54, and 55 are pending and are under examination.

Withdrawn Rejections

2. The rejections of claims 41, 45, 47, and 48 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 34, 35, 37-40, 42-44, 46, 49-51, 54, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34, step b) is confusing and lacks clear antecedent basis in reciting, "such that a plurality of different optical signaling components become bound to said feature" because step a) recites that there is "at least one optical signaling component". Hence, it is unclear how the "at least one optical signaling component" becomes a plurality of different signaling components that become [physically] bound to a feature. It appears that there should be "more than one" rather than "at least one" optical signaling component in step a), since an embodiment of "one optical signaling component" is encompassed in the claim. It is therefore, unclear how the at least one optical signaling component can pluralize into a plurality of optical signaling components, much less different ones, by virtue of binding a probe comprising a binding element and an optical signaling component. Same analogous comments and problems apply to step c) in reciting, "different optical signaling components", step d) in reciting, "plurality of light beams" and "plurality of different discriminable characteristics", step e) in reciting, "plurality of light beams" and "plurality of images", step f) in reciting, "plurality of images", and step g) in reciting, "plurality of images" and "plurality of different optical signaling components." See also claims 37, 39, and also claim 40 in reciting, "at least one optical signaling component, one of which includes a different optical signaling component."

Claim 42, step b) is confusing and lacks clear antecedent basis in reciting, "such that at least two different optical signaling components become bound to said feature" because step a) recites that there is "at least one optical signaling component". Hence, it is unclear how the "at least one optical signaling component" becomes at least two

different signaling components that become [physically] bound to a feature. It appears that there should be "at least two" rather than "at least one" optical signaling component in step a), since an embodiment of "one optical signaling component" is encompassed in the claim. It is therefore, unclear how an at least one optical signaling component can pluralize into "at least two optical signaling components, much less different ones, by virtue of binding a probe comprising a binding element and an optical signaling component. Same analogous comments and problems apply to step c) in reciting, "plurality of different optical signaling components", step d) in reciting, "plurality of light beams" and "plurality of different discriminable characteristics", step e) in reciting, "plurality of light beams" and "plurality of images", step f) in reciting, "plurality of images", and step g) in reciting, "plurality of images". See also claims 43, 50, and 51.

All comments and problems set forth for claims 34 and 42, apply to claims 54 and 55, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 34, 35, 37-40, 42-44, 46, 49-51, 54, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Garini et al. (US 6,066,459).

Garini et al. disclose a method for detecting a feature or a cellular component, in an object or a cell, using an imaging system. Garini et al. teach providing at least one probe having a fluorescent label or dye, i.e. optical signaling component, conjugated thereto. Garini et al. teach using different fluorophores for each probe or a plurality or combination of different fluorophores for every probe (different optical signaling components). See Abstract, column 1, lines 24-48, and column 13, lines 13-30. The probe selectively binds to at least a portion of the cellular component, i.e. chromosome in the cell nucleus, within the cell. The labeled probe is then contacted with the cell so as to bind the labeled probe to the selected cellular component. Fluorescence excited by white or coherent light is detected in few narrow spectral bands, and collected from the cell along a collection path, wherein the light collected corresponds to each of the plurality of different fluorescent dye combinations or different optical signaling components. The collected light is focused to produce an image of the cell nucleus, which is viewed through a fluorescence microscope that is optically connected to an imaging system (spectrometer). Locations of the labeled probe bound to the selected portion of the cellular components that are imaged are optically and spectrally discriminated. Therein, multiple spectra each representing a different probe, are simultaneously collected and measured. The imaging system is capable of obtaining a spectrum of each pixel of the cell nucleus (see column 29, lines 27-46 and column 34, line 29 to column 35, line 21). The signal is then analyzed to determine if a spectral

component from the combination of fluorophore dyes that are conjugated to the labeled probe that bound, are present in the image, to hence establish that the cellular component is integral part of the cell. The method is highly sensitive both in spatial and spectral resolutions; hence is capable of simultaneous detection of combinations of fluorophores. See especially column 6, line 58 to column 7, line 46 and column 8, lines 5-13.

In as far as the recitation of "dispersing the light that is traveling along the collection path into a plurality of light beams, as a function of a plurality of different discriminable characteristics of the light, as recited in amended claims 34 and 42, it is noted that Garini et al. teach that there are three basic types of spectral dispersion methods that is considered for spectral bio-imaging systems used in his method including: 1) spectral grating, 2) spectral filters, and 3) interferometric spectroscopy, the latter of which is best suited to implement Garini's claimed method. However, Garini et al. also provide that grating and filter-based spectral bio-imaging systems are also found to be useful in certain applications of this method (see column 2, lines 50-58). Accordingly, Garini et al. is deemed to anticipate the claimed invention.

In as far as the recitation of "there is a relative motion between the object and an apparatus employed to collect the light", as recited in claims 54 and 55, it appears that the object and apparatus employed to collect light are inherently required to be at relative motion with each other if simultaneous spectral dispersion imaging of different objects are to be analyzed. Since Garini et al. teach all the elements recited in the claims, absent evidence to the contrary, it is deemed that the imaging system as taught

by Garini et al. exhibits relative motion between the object and the apparatus; hence, Garini et al. is deemed to inherently anticipate the claimed invention.

Response to Arguments

5. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive.

A) Applicant requests explanation as to why claims 52 and 53 have remained withdrawn from consideration as claims drawn to non-elected invention, rather than rejoined with elected groups for examination on the merits.

In regards to claims 52 and 53, being restricted and withdrawn from further consideration for being drawn to using "a set of labeled probes", it is maintained that these method claims are independent and distinct from those currently being examined by virtue of their difference in structural and functional requirements in encompassing use of "a set", i.e. a cocktail of labeled probes, which is not structurally and functionally required in the claims currently under examination. While the recitation of "at least one probe" and "at least one optical signaling component" may arguably appear to encompass "more than one probe" and "more than one optical signaling component", it is understood in the art that the mere recitation of "at least one probe" encompassed with the groups being examined, specifically exclude "a set of labeled probes" which can bifurcate into claim limitations encompassing "a set of labeled probes [having a plurality of the same or different probes, each conjugated to a plurality of the same or

different optical signaling components]" which is encompassed in the non-elected and withdrawn claims. Alternatively, if Applicant intends to state for the record that one group is an obvious variation of the other, for purposes of withdrawing the restriction requirement, then claims 52 and 53 would be rejoined, with the understanding that prior art teaching or suggestion of one embodiment, i.e. using at least one probe ..." would render the other embodiment, i.e. using a set of labeled probes ..." an obvious variation of species of the other.

B) Applicant argues that the recitation of "labeled probe" in claims 34 and 42 are clear and definite, because it is understood and recited that the "at least one labeled probe" comprises a binding element and at least one optical signaling component. Applicant argues that the specification as filed clearly discloses the specific conditions that are required in "exposing ... at least one probe under conditions that cause ... a plurality of different optical signaling components to become bound to a feature". According to Applicant, two conditions disclosed in which a plurality of optical signaling components can be bound to the same feature includes :1) a plurality of different probes, at least one (or each) of which includes a different optical signaling component can be bound to the feature, and 2) a single probe including two different optically signaling components can be bound to the feature.

First of all, the question of the definiteness of "at least one labeled probe" is not isolated in its recitation on its own, but rather is indefinite in view of its structural

relationship with the rest of the elements in the claim, including "at least one signaling component" and then "a plurality of optical signaling components." As set forth supra, it remains unclear how "[at least] one optical signaling component" multiplies physically into "a plurality of different optical signaling components." While Applicant has pointed to examples, embodiments, and figures in the specification of how a plurality of different optical signaling components should be embodied, nowhere has it been shown how "a binding element having one signaling component" encompassed by the claimed invention binds to a feature then physically multiplies its effect into a plurality of different optical signaling components. In all examples and embodiments set forth in the specification including the two requirements exemplified by Applicant in his argument in page 11, lines 23-28, nowhere is it exemplified how an original one optical signaling component as encompassed and claimed, is able to provide a plurality of different optical signaling components effect. While 1) a plurality of different probes, at least one (or each) of which includes a different optical signaling component, and 2) a single probe including two different optically signaling components, can be bound to the feature to effectively provide a plurality of different optical signaling components, neither embodiment appears to be clearly defined and recited in the rejected claims. The claims as recited encompassing the limitation "a binding element and [at least] one optical signaling component, are not consistent with the exemplified teaching in the specification and cannot appear to provide such effect. Accordingly, the indefiniteness rejection has been maintained.

C) Applicant argues that Garini et al. does not teach or suggest the claimed invention because Garini et al. does not employ the use of spectral dispersion element, or simultaneously detecting plurality of spectrally dispersed images, as recited in the amended claims. Applicant specifically contends that Garini's technique is based on collecting a plurality of different spectral images sequentially over time, rather than simultaneously as recited in the claimed invention.

Contrary to Applicant's argument, Garini et al. at column 2, lines 50-58 provides that interferometric spectroscopy is a form of spectral dispersion method, which is consistent with the new limitations recited in the rejected claims. Additionally, while interferometric spectroscopy is the preferred method, Garini appears to also suggest application of spectral grating and spectral filters in his method. Garini et al. at column 7, lines 38-42 also teach that the optical differences (spectral images) between two coherent beams generated by the interferometer system is scanned simultaneously for all the pixels of the cell nucleus (and not sequentially, as contended by Applicant).

D) Applicant argues that while Garini discloses detection of multicolored probes, it is not clear that Garini teaches and suggests being able to distinguish intensity among multicolored probes which is taught in the claimed invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., claimed method ... being able to distinguish intensity among multicolored probes) is not recited in the rejected claims. Nowhere in the rejected claims suggests such

teaching that renders the claimed invention distinct from that taught by Garini et al. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
August 21, 2006